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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,384	12/23/2003	Richard Eric Rothman	001107.000412	7753

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WASHINGTON, DC 20001

EXAMINER

WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/743,384	Applicant(s) ROTHMAN ET AL.	
	Examiner Cynthia B. Wilder, Ph.D.	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed 11/14/2006 is acknowledged and has been entered. Claims 1, 4, 5, 6, 16, 19, 20, 21 have been amended. Claims 43-52 have been canceled. Claims 1-42 are pending. All of the amendments and arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

This action is made FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Objections and Rejections

3. The objection to the specification is withdrawn in view of Applicant's amendment. The new matter rejection under 35 USC 112 first paragraph is withdrawn in view of Applicant's amendment to the claims. The claim rejection under 35 USC 112 second paragraph is maintained and discussed below.

Claim Rejections - 35 USC § 112 second paragraph

4. Once again claims 1-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 1-42 are confusing in claims 1 and 16 for the limitation:

"wherein the primers when in the presence of a *S. aureus* 16S rRNA gene amplify a segment of the gene comprising a conserved region and a first divergent region, wherein the conserved region comprises at least 18 contiguous nucleotides which are at least 80% identical among at least 10 eubacterial species wherein

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the first divergent region comprises at least 10 contiguous nucleotides and differs by at least 3 nucleotides from a second divergent region found in *Bradyrhizobium japonicum* 16S rRNA gene",

because it is unclear as to what "segment" of the *S. aureus* 16S rRNA gene the primers are actually amplifying or how amplifying these segments relate to determining species source of eubacterial DNA. It appears that Applicant has described properties of the *S. aureus* 16S rRNA gene, but the nexus between these properties as it relates to the divergent region of *Bradyrhizobium Japonicum* and the step of amplifying a segment of *S. aureus* 16S rRNA gene with primers is unclear. It appears that the primer can amplify any segment of the *S. aureus* 16S RNA gene. Likewise, if *S. aureus* is not present, does the method still operate or is *S. aureus* a requirement for the method? How this relates to determining a first species of eubacterial in a sample is ambiguous and unclear. Clarification is required.

Applicants' Traversal

5. Applicant traverses the rejection on the following ground: Applicant states that in the presence of a template from *S. aureus* 16S rRNA gene the primer amplifies a segment that comprises a conserved region and a divergent region. Applicant states that the conserved region and the divergent region are defined by similarities to at least 10 eubacterial species (conserved) or divergence from *Bradyrhizobium* (divergent), respectively, *S. aureus* 16S rRNA gene contains more than one such segment, but not any segment of the gene will fulfill these criteria. Applicant states that an example of one such segment is recited in claim 3, nucleotides 890-1051. Applicant states that the method of the present claims does not recite or specify the amplifying of a segment of *S. aureus* 16S rRNA gene. Applicant states that the ability to amplify *S. aureus* 16S rRNA gene is a property of the primers. Applicant states that the recited step of amplifying

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template DNA is from *S. aureus*. Applicant states that the template DNA which amplified can be from any eubacteria. Applicant states that in fact, the purpose of the method is to detect and determine species of a eubacterial (which may be unidentified at the outset of the assay) by virtue of detecting an amplifying its rRNA.

Examiner's response

6. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons that follow: In response to Applicant's arguments, the Examiner maintains that the claims are confusing overall because a clear nexus between the steps is unclear. Specifically, it is unclear how the claim method operates to detect and determine species source of eubacterial DNA in a sample. Firstly, it is confusing the relevance of the *S. aureus* 16S rRNA because the claims recited that "the primer when in the presence of a *S. aureus* 16S rRNA gene amplify a segment of the gene. If the primers are not in the presence of *S. aureus* does the method still operate or is *S. aureus* a requirement for determining various eubacterial DNA species? Secondly, it is unclear which segments of the *S. aureus* gene the primers amplify. The examiner maintains that the limitation "wherein the primer when in the presence of a *S. aureus* 16S rRNA gene amplify a segment of the gene comprising a conserved region and a first divergent region...." appears to be a property of the *S. aureus* gene and does not provide any characteristics of the segments or limit the segment being amplified by the primers. Therefore, it appears that any segment of the primer can be amplified by the primers regardless to whether or not it is in a conserved region of the *S. aureus* gene. Thirdly, since it is unclear what is being

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amplified by the primers, the nexus between the presence or absence of *S. aureus* and the hybridization of probes to divergent regions of *Bradyrhizobium Japonicum* is unclear.

Conclusion

7. No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

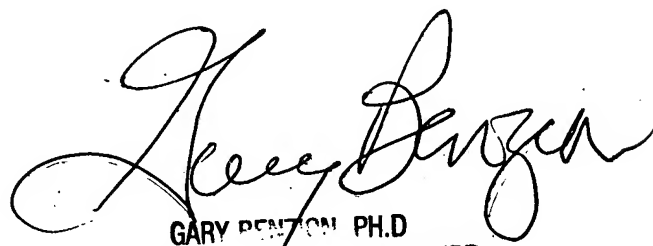
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cbw



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